PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification [4] :		(11) International Publication Number: WO 88/ 10108
A61F 5/56, A61B 5/08 F04B 49/06	A1	(43) International Publication Date: 29 December 1988 (29.12.88)

(21) International Application Number: PCT/AU88/00215

(22) International Filing Date: 27 June 1988 (27.06.88)

(31) Priority Application Numbers: PI 2730
PI 4234

(32) Priority Dates: 26 June 1987 (26.06.87)
8 September 1987 (08.09.87)

(33) Priority Country: AU

(71) Applicant *(for all designated States except US):* TRAVENOL CENTRE FOR MEDICAL RESEARCH [AU/AU]; 376 Lane Cove Road, North Ryde, NSW 2113 (AU).

(72) Inventors; and
(75) Inventors/Applicants *(for US only) :* SULLIVAN, Colin, Edward [AU/AU]; 27 Wharf Road, Birchgrove, NSW 2041 (AU). LYNCH, Christopher [AU/AU]; 376 Lane Cove Road, North Ryde, NSW 2113 (AU).

(74) Agent: F.B. RICE & CO.; P.O. Box 117, Balmain, NSW 2041 (AU).

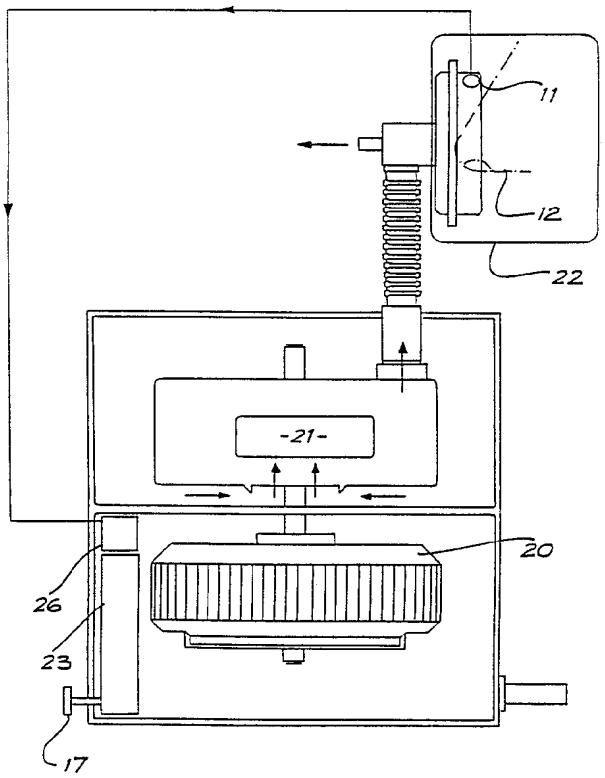
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DEVICE FOR MONITORING BREATHING DURING SLEEP AND CONTROL OF CPAP TREATMENT

(57) Abstract

A CPAP apparatus including: a variable pressured air source including an air compressor and means to vary the air pressure delivered therefrom (23); a nose piece (22) for sealed air communication with a patient's respiratory system (12); an air communication line from the air source (21) to the nose piece (22); a sound transducer (11) adapted to be in sound communication with the patient's respiratory system (12); and a feedback system (26) controlling the output pressure of the air source (21) in response to an output from the transducer (11) so as to increase the output air pressure from said air source (21), in response to detection of sound indicative of snoring, in accordance with a predefined procedure.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BG	Bulgaria
BJ	Benin
BR	Brazil
CF	Central African Republic
CG	Congo
CH	Switzerland
CM	Cameroon
DE	Germany, Federal Republic of
DK	Denmark
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
HU	Hungary
IT	Italy
JP	Japan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
LI	Liechtenstein
LK	Sri Lanka
LU	Luxembourg
MC	Monaco
MG	Madagascar
ML	Mali
MR	Mauritania
MW	Malawi
NL	Netherlands
NO	Norway
RO	Romania
SD	Sudan
SE	Sweden
SN	Senegal
SU	Soviet Union
TD	Chad
TG	Togo
US	United States of America

"DEVICE FOR MONITORING BREATHING DURING SLEEP AND CONTROL OF CPAP TREATMENT"

BACKGROUND ART

The present invention relates to the diagnosis and treatment of partial or complete upper airway occlusion, a condition where the upper airway collapses, particularly under the reduced pressure generated by inhalation. This is most likely to happen during unconsciousness, sleep or anaesthesia.

A particular application of the present invention is to the diagnosis and/or treatment of snoring and sleep apnea. Sleep apnea is characterised by complete occlusion of the upper airway passage during sleep while snoring is characterised by partial occlusion. Obstructive sleep apnea sufferers repeatedly choke on their tongue and soft palate throughout an entire sleep period resulting in lowered arterial blood oxygen levels and poor quality of sleep. It should be realised that although the following specification discusses sleep apnea in detail, the present invention also applies to the diagnosis and treatment of other forms of upper airway disorders.

Reference to international patent publication WO 82/03548 will show that the application of continuous positive airway pressure (CPAP) has been used as a means of treating the occurrence of obstructive sleep apnea. The patient is connected to a positive pressure air supply by means of a nose mask or nasal prongs. The air supply breathed by the patient, is at all times, at slightly greater than atmospheric pressure. For example, gauge pressures will typically be within the range of 2cm - 25cm. It has been found that the application of continuous positive airway pressure provides what can be described as a "pneumatic splint", supporting and stabilizing the upper airway and thus eliminating the occurrence of upper airway occlusions. It is effective in

eliminating both snoring and obstructive sleep apnea and in many cases, is effective in treating central and mixed apnea.

The airway pressure required for effective CPAP therapy differs from patient to patient. In order to discover the airway pressure which is most effective for a particular individual, the practice has been for the patient to undergo two sleep studies at an appropriate observation facility such as a hospital, clinic or laboratory. The first night is spent observing the patient in sleep and recording selected parameters such as arterial oxygen saturation, chest wall and abdominal movement, air flow, expired CO_2, ECG, EEG, EMG and eye movement. This information can be interpreted to diagnose the nature of the sleeping disorder and confirm the presence or absence of apnea and where present, the frequency and duration of apneic episodes and extent and duration of associated oxygen desaturation. Apneas can be identified as obstructive, central or mixed. The second night is spent with the patient undergoing nasal CPAP therapy. When apnea is observed the CPAP setting is increased to prevent the apnea. The pressure setting at the end of the sleep period, i.e. the maximum used, is deemed to be the appropriate setting for that patient. For a given patient in a given physical condition there will be found different minimum pressures for various stages of sleep in order to prevent occlusions. Furthermore, these various pressures will, in fact, vary from day to day depending upon the patient's physical condition, for example, nasal congestion, general tiredness, effects of drugs such as alcohol, as well as their sleeping posture. Thus the appropriate pressure found in the laboratory is necessarily the maximum of all these minimum pressures for that particular night and is not necessarily the ideal pressure for all occasions nor

for every night. It will generally be higher than necessary for most of the night.

Also patients must be able to operate a CPAP system to deliver appropriate airway pressure at their home where their general physical condition or state of health may be quite different to that in the sleep clinic, and will certainly vary from day to day. The patient's physical condition often improves due to CPAP therapy. It is often the case that after a period of therapy the necessary airway pressure can be reduced by some amount while still preventing the occurrence of obstructive sleep apnea. However, the prior art provides no facility to take advantage of this fact other than by regular diagnostic sleep periods in a sleep clinic or hospital.

The long term effects of CPAP therapy are unknown so it is desirable to keep the airway pressure as low as practicable, particularly if a patient requires long term treatment. Lower airway pressures also result in a lower face mask pressure which is generally more comfortable for the patient. It has been found that CPAP induces patients to swallow and this inducement to swallow can be reduced by lowering the airway pressure. Thus it is desirable to use the lowest practicable airway pressure that is effective in preventing airway occlusion during CPAP therapy for the comfort and, possibly, the long term safety of the patient. Also, a lower airway pressure requires less energy consumption and a less complex and therefore less expensive apparatus which is generally quieter.

Low airway pressures are also desirable before and during the early stage of each sleep period as the increased comfort of an initially lower airway pressure allows the patient to more easily fall asleep. When a patient undergoing CPAP opens his mouth with pressurized air being forced through the nose the pressured air exits

out of the mouth producing an unpleasant sensation. This can occur when the patient puts on the mask connected to the pressured air supply before falling asleep and some patients will therefore leave the mask off for as long as possible and may in fact fall asleep without wearing the mask and therefore without the benefits of the CPAP therapy.

Presently available CPAP units do not address this problem and so there is a need to provide a CPAP device which will be more acceptable to the patient before and during initial sleep by operating at an initially low pressure but automatically increasing to an appropriate therapeutic pressure before apnea occurs.

In addition to the problems associated with administering CPAP therapy there exists the inconvenience and cost of diagnosis which is currently undertaken by overnight observation at a sleep clinic or the like. Hence a simple means whereby a patient's apnea problem can be diagnosed at home without supervision is clearly desirable as well as a CPAP device which will deliver a continuously minimum appropriate pressure for substantially the entire period of therapy.

Devices are available to detect apnea. For example, International Patent publication WO/86/05965 discloses an apparatus which includes acoustic respiration sensors, background sound sensors and movement sensors. Such apparatus are capable of detecting breathing sounds, comparing those sounds with body movements and background noises and by further comparing the results with a data base of information, to indicate whether the patient is undergoing a normal or abnormal breathing pattern. Such apparatus can sound an alarm on the occurrence of apnea.

Another device which could be readily adapted to detect and record the occurrence of apneic episodes is disclosed in US Patent No. 4,537,190. That apparatus is

responsive to the CO_2 levels in exhaled air during respiration and is also responsive to the absence of respiration (i.e. apnea) in which case it can switch on a ventilator.

These devices are deficient in that they do not take advantage of the indication of apnea obtained exclusively from a recording from a single sound transducer (microphone) preferably located in the CPAP nose mask or prongs that can be interpreted by a skilled physician. The inherent simplicity of this form of measurement makes it safe and practicable for anybody to use in their own home with a minimum of prior instruction.

Although diagnosis in a sleep clinic as outlined above is beneficial, it has some deficiencies. A patient is likely not to sleep in a fully relaxed state in an unfamiliar environment and a single night is insufficient to obtain a pressure setting that will be optimal in the long run. Thus home therapy at the pressure setting arrived at in this way is likely to be less than 100% effective on some occasions and higher than necessary for a substantial portion of the time. The cost and inconvenience of a sleep study in a hospital setting are to be avoided if possible.

A skilled physician can usually recognise the symptoms of sleep apnea from questioning and examining a patient. Where no other indications are present there is very little risk in attempting nasal CPAP therapy without further testing as the treatment is fail safe and non-invasive. However, a very useful intermediate step would be to analyse the pattern of respiratory sounds over one or more full nights of sleep. Interpretation of these patterns together with questioning and examination will, in many cases, provide sufficient confirmation of apnea to prescribe nasal CPAP therapy. If nasal CPAP eliminates the symptoms of day time sleepiness (as assessed by the

patient) and of apneic snoring patterns (as assessed by analysis of recorded respiratory sounds while on nasal CPAP), the treatment can be continued. Further check-ups can be conducted at intervals recommended by the physician.

The measurement of other parameters would provide further information to assist diagnosis and the acoustic recording described above can readily be used in conjunction with other monitors such as ECG and/or pulse oximetry. Suitable monitors are available to measure both these parameters in the home but with increased information comes much higher cost of equipment and increase complexity in using the equipment. The correlation between reduced oxygen saturation and apnea is sufficiently well established to infer oxygen desaturation from the confirmation of an apneic event.

Diagnosis which are not conclusive from examination and home monitoring will continue to be confirmed from full sleep studies in a Sleep Disorders Centre.

Thus the prior art monitors and methods are deficient at least in that the resulting therapy is not 100% effective at all times, it is delivered at higher pressure than necessary for substantial periods, the equipment is expensive and has required diagnosis in specialised clinics.

DISCLOSURE OF INVENTION

The present inventors have recognized the detection of the noise of snoring or more particularly snoring patterns as a reliable parameter for detecting apneas as well as the imminent onset of apneic episodes. Characteristic snoring patterns can be associated with various sleep conditions including apnea and in fact in most (perhaps 95%) of sleep apnea sufferers, distinctive snoring patterns closely precede apneic episodes as will be later discussed.

A pressure transducer such as a microphone is a

suitable detector of these characteristic snoring sounds, and in particular the sounds of snoring patterns. Furthermore, the quality of the sounds monitored can be enhanced by placing the microphone within an enclosure which is in sound communication with a patient's respiratory system. By enclosing the microphone, a physical noise barrier isolates the microphone from external sounds. If the enclosure is in sound communication with the patient's respiratory system the natural stethoscope effect of the patient's respiratory system is thereby exploited. A further benefit of such a device is that the microphone is not in direct contact with any part of the patient's body. Thus, relative movement between the microphone and the patient's body, which is a noise source as far as monitoring is concerned, can be avoided.

Monitoring of a patient's snoring patterns alone can in many instances provide information indicative of his/her condition, whether he/she suffers mild, medium or extreme apneic episodes, how often the episodes occur and therefore whether CPAP therapy will be beneficial. A snoring monitor can accordingly be used at least as a preliminary diagnostic tool with or without monitoring other physiological parameters to provide information on the frequency and severity of snoring, hypopnea and apnea in a patient. Its simplicity and inexpensive nature allows it to be used at home in the patient's usual environment without the expense of a night in a sleep clinic. In some cases, e.g., where unusual snoring patterns are encountered, the diagnosis of the data from the snoring monitor will not be conclusive and the traditional full diagnosis in a sleep clinic will be required.

Thus, in one form of this invention there is provided a diagnostic device comprising a nose piece substantially

fluidly sealable to, or in sealed fluid communication with, the nasal air passages of a patient, a sound transducer in sound communication with the interior of the nose piece so as to be in use in sound communication with the respiratory system of the patient and to detect, and produce a signal responsive to the sounds of patient snoring, and recording equipment associated with the sound transducer for recording information indicative of the signal.

In one preferred embodiment of the diagnostic device, the intensity of the signal is recorded with respect to time. In another embodiment of the diagnostic device the microphone output is fed through an amplifier or filter to differentiate normal breathing sounds from those indicative of snoring, and the intensities and time pattern of the differentiated sounds are recorded. In a further embodiment of the diagnostic device the frequency and duration of airway occlusions are calculated by preprogrammed processing of the detected signal, the processed signal is recorded as a time chart or a table interpreted by the physician.

Thus in a number of cases such a snoring monitor provides an effective substitute for the traditional first night in the sleep clinic. Where diagnosis indicates CPAP therapy to be appropriate the patient can go straight to the traditional second night at the sleep clinic so as to determine their appropriate CPAP setting for their condition, or they could commence use of an automatic CPAP device such as the unit described hereunder.

The monitoring of snoring patterns is useful not only for recording information regarding those patterns for diagnostic purposes but is also useful in that certain snoring patterns are a precursor to most apneic episodes in a large proportion of sleep apnea victims. Thus, an effective CPAP device can be controlled by a feedback

system in which snoring patterns are monitored and CPAP pressure is raised at the detection of predefined snoring patterns so as to provide increased airway pressure before, and in fact generally prevent the occurrence of, apneic episodes.

Thus, in another form of the invention there is provided in a CPAP apparatus a feedback control comprising a sound monitoring device in sound communication with the respiratory system of a patient when using the apparatus, and a processor responsive to output from the sound monitoring device so as to control CPAP pressure according to patient requirements as determined by output from the sound monitoring device in order to prevent apneic episodes.

Preferably, the feedback control is co-operative with a variable speed air compressor of the CPAP apparatus, the processor regulating the speed of the compressor when in use by increasing speed in response to a said signal equivalent to a preprogrammed signal indicative of a predetermined snoring pattern.

Preferably, the control system furthermore decreases speed of the air compressor in the absence of the signal after a period of time in accordance with the predefined procedure.

In another form of the feedback device of the invention there is provided a CPAP apparatus including a variable speed air compressor, a nose piece for sealed air communication with a patient's respiratory system, an air line from the compressor to the nose piece, an enclosed microphone connected to the air line so as to be in sound communication with the patient's respiratory system, and a feedback system controlling the speed of the air compressor in response to an output from the microphone so as to increase compressor speed in response to detected sound indicative of heavy snoring in accordance with a

predefined procedure. Preferably the feedback system reduces the speed of the air compressor in response to an absence of the said sound in accordance with the predefined procedure.

Disadvantages in the prior art are also ameliorated by a further aspect of the invention which provides a variable speed air compressor and control system in the CPAP apparatus, the control system regulating the speed of the compressor when in use by increasing its speed in accordance with a predefined procedure whereby the commencement of operation of the compressor occurs at a preselected minimum speed with a gradually increasing compressor speed over a preselected period of time to a preselected maximum speed.

This embodiment of the invention provides an advantage in that the patient is exposed to a comfortably low pressure before falling asleep and during initial stages of sleep while the necessary therapeutic pressure is reached by the time it is required.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will now be described in detail by way of reference to the attached drawings in which:

Fig. 1a is a schematic sectional view of one embodiment of a snoring detection apparatus in accordance with the present invention;

Fig. 1b is a schematic sectional view of another embodiment of a snoring detection apparatus in accordance with the present invention;

Fig. 2a is a slow recording of sound levels obtained using the monitor of the present invention for a patient suffering from sleep apnea;

Fig. 2b shows the correlation of sound patterns and blood oxygen levels during a period of repetitive obstructive apnea;

Fig. 3 is a diagram of a further embodiment of the

present invention;

Fig. 4 is a circuit diagram of the device of Fig. 3;

Fig. 5 is a diagram of an embodiment of another aspect of the invention; and

Fig. 6 is a circuit diagram of the device of Fig. 5.

BEST MODE OF CARRYING OUT THE INVENTION

Fig. 1a illustrates a snoring detection device 10 comprising a microphone 11, in sound communication with the container 12 of a nose mask. Air, being inhaled by the patient, enters the nasal passageways 14 through the opening 13 in the nose mask 12 and is exhaled in the reverse direction. As the airway extends from the source of snoring sounds within the patient's body, through the nasal passages 14 and out of the opening 13 in the nasal mask, the microphone 11 is ideally located to take advantage of the natural stethoscope formed by the enclosed airway. Hence the snoring and breathing sounds are focused and concentrated by this arrangement. Alternatively, the microphone 11 may be located within, or attached externally of, a nasal prong device as illustrated in Fig. 1b. The detection device 10 can be used in a diagnostic device or a feedback control. In the case of the detection device 10 being used in diagnostic equipment there is connected to the microphone 11 an electronic processor/recorder which records signals from the microphone 11 either on a time basis or after preprogrammed processing so as to record for example tables of indexes such as the number of apneic episodes, their duration, etc. The recorded data can then be reviewed by the physician for diagnosis.

Fig. 2a shows a graph representing sound amplitudes recorded from the snoring detection device 10. The major calibration in the time scale direction represents two minutes.

The effect of blower motor noise can be diminished or

completely removed by setting a low gain on the recording device or passing the signal through an amplitude filter to effectively ignore all sounds below a particular minimum amplitude or by passing the signals through a low pass frequency filter to effectively ignore sounds above its cut-off frequency. An alternative method is to use a sound attenuator in the air line proximate the blower.

Part A of Fig. 2a is indicative of normal breathing, part B indicates soft to moderate snoring, part C shows constant loud snoring and part E shows periods of silence punctuated by snoring. In section D of the chart of Fig. 2a, it can be seen that the breathing sound intensity rises and falls. This is indicative of obstructive hypopnea, a condition in which the breath-by-breath intensity decreases progressively, and then increases. In this pattern the decreasing intensity of the snoring occurs when the upper airway is almost, but not entirely, sucked closed by strong inspiratory efforts. This pattern is a "pre-apneic" pattern.

The following part E, is therefore quickly interpreted by a skilled physician as being indicative of sleep apnea, with periods of airway occlusion which terminate with one or more loud breathing sounds followed by further occlusions.

The correlation between snoring patterns and arterial oxygen is shown in Fig. 2b. Clearly the snoring patterns are an accurate parameter for detecting imminent apneic episodes, and more importantly periods of low oxygen supply to the brain and other organs.

Thus recorded information derived from the signal of the device 10 can be used for diagnostic purposes, such as initial diagnosis of sleep apnea, without the need for the patient to stay overnight at an observation facility. The sound patterns can be analysed by a programmed microprocessor within the diagnostic unit so as to record

tables of indexes such as number of apneic episodes, their duration and time of occurrence. This is of economic significance because the cost of one overnight observation is comparable to the purchase price of a CPAP device.

The nose prongs and mask 12 are convenient forms of containers for the monitor device 10 however the container could take any other convenient form.

Furthermore, diagnostic apparatus in accordance with the present invention is suited for use by a patient with minimal supervision and therefore may be used successfully at home, the recorded diagnostic information being conveniently presented for expert analysis.

In Fig. 3, a CPAP apparatus embodying the invention is illustrated. The CPAP unit comprises a motor 20 which drives a blower 21. The speed of the motor 20 is controlled by an electronic speed control unit 23. As an increase in motor speed also increases the blower speed which in turn increases the output air pressure of the blower 21, the speed control unit can be manipulated to vary the output pressure of the blower 21. The CPAP device also includes a snoring detection means 22 wherein sounds are detected by a microphone 11. The snoring detection means 22 is conveniently in the form of the previously described device 10. Electrical impulses are fed from said microphone 11 to an amplifier/filter/processor unit 26 which generates an electrical signal when snoring sounds occur. The motor speed control means is electrically connected to the snoring detection device 22 and increases the speed of the electric motor 20 by an analogue means in response to the electrical signal generated by the snoring detection device. Accordingly, the output pressure of the CPAP unit increases in response to detection of snoring.

When a snore or sequence of snores is detected by the snoring detection means 22 a signal is generated. The

speed control unit 23 increases the speed of the fan motor and the output pressure is increased. As snoring is caused by vibration of the soft palate, it is therefore indicative of an unstable airway and, as previously described, is a warning signal of the imminence of upper airway occlusion in patients that suffer obstructive sleep apnea. Snoring is itself undesirable not only as it is a disturbance to others but it is strongly believed to be connected with hypertension. If the resultant increase in CPAP pressure is sufficient to completely stabilize the airway, snoring will cease. If a further snoring sound is detected, the CPAP pressure is increased again. This process is repeated until the upper airway is stabilized and snoring ceases. Hence, the occurrence of obstructive apnea can be eliminated by application of a minimum appropriate pressure at the time of use.

In order to ensure that the CPAP pressure is maintained at a level as low as practicable to prevent the onset of apnea, the preferred embodiment also includes a means to decrease the pressure if an extended period of snore free breathing occurs. For example, this can be done by automatically reducing the CPAP pressure at a gradual rate as long as snoring is not detected. The rate at which the CPAP pressure is decreased in the absence of snoring is preferably much less than the rate at which it is increased when snoring is detected. This can be achieved, for example, by the amplifier/filter/processor unit 26, in the absence of an electronic signal from the microphone 11, continuously gradually reducing the blower speed over a period of time but increasing the blower speed in incremental steps each time a snore is detected by the microphone 11.

In use, a patient may connect himself to the CPAP unit and go to sleep. The CPAP pressure is initially at a minimum operating value of, for example, approximately 3cm

H_2O gauge pressure so as not to cause the previously mentioned operational problems of higher initial pressures. Not until some time after going to sleep, and the patient's body relaxes, will the airway start to become unstable and the patient start to snore. The detection apparatus 22 will then respond to the snore, or snore pattern, and via the processor 26 increase the motor speed such that CPAP pressure increases by 1cm H_2O for each snore detected. The CPAP pressure can be increased relatively rapidly, if the patient's condition so requires, to a working pressure of the order of 8-10cm, which is a typical requirement. An upper pressure limiting device can be incorporated for safety. Also, for ease of monitoring the variation over time in patient conditions, a paramater such as pressure output can be recorded in some convenient retrievable form for periodic study by the physician.

If for example in the early stages of sleep some lesser CPAP pressure will suffice, the CPAP unit of the present invention will not increase the pressure until needed, that is, unless the airway becomes unstable and snoring recommences no increase is made to the airway pressure.

By continuously decreasing the CPAP pressure at a rate of, for example, 1cm H_2O each 15 mins. in the absence of snoring the pressure is never substantially greater than that required to prevent apnea. However, when a snore, or snoring patterns, is detected. The decreasing CPAP pressure mode will be completely overwhelmed by a greater increase, about 1 cm H_2O predetected snore or snoring pattern. Once a stable sleeping pattern is achieved, the preferred embodiment will then continually test to ensure that the CPAP pressure is as low as is practicable. Should the CPAP pressure be decreased to such an extent that the upper

airway becomes unstable and snoring recommences, the pressure is reincreased to ensure that apnea is prevented, it being remembered that the snoring pattern is a precursor to apneic episodes.

The flexibility of the invention can be illustrated by the following example.

It is known that a patient's maximum propensity to suffer sleep apnea occurs during REM sleep. An airway that was otherwise stable at a given CPAP pressure may become unstable during REM sleep. Should this happen snoring will set in before apnea occurs. In such circumstances, the present invention will raise the CPAP pressure in response to the snoring, thus preventing the onset of apnea. After the REM sleep passes, the patient's airway becomes more stable and the higher airway pressure is no longer required. In such circumstances, the CPAP pressure will be gradually reduced until the first sign of snoring reoccurs at which point the pressure will again be increased.

A patient normally makes at least one loud snort or snoring sound at the end of an occurrence of apnea and the present invention will respond to this unusually loud sound to increase the CPAP pressure. Thus even if apnea should occur without the usual precursor of snoring, the airway pressure can still be adjusted upward in response to the abnormally loud breathing sounds generated at the end of the apneic period.

The present invention thus provides a CPAP device which modifies the CPAP pressure according to variations in a patient's requirements throughout an entire sleep period. It will be clear to those skilled in the art that the present invention can cope with the variation in airway pressure requirements such as may occur during a single sleep period, it will also be able to cope with variations in CPAP pressure requirements due to a general

improvement or deterioration in a patient's general condition as may take place over a longer period of time.

Fig. 5 illustrates in block form the circuitry of the CPAP device of Fig. 4. A snoring detection apparatus 22 is comprised of the microphone 11 attached to the nose mask 12. The electrical signals of the microphone 11 are sent to a Filter/Amplifier/Processor 26 which generates a control signal indicative of the recognition of a snoring pattern equivalent to a predetermined pattern.

Such control signals are sent to a feedback speed controller 23. The speed controller 23 comprises a ramps generator and voltage to frequency converter 24 for control of a switch mode power supply (SMPS) 15, which provides the power to run the motor 20 turning the blower 21.

The maximum output of the SMPS 15, and therefore the maximum pressure delivered to the mask 12, is limited by a pressure-time control 17.

In another aspect of the invention, shown in Figs. 5 and 6, there is provided a control circuit 33 comprising a delay control 25, a timer 24, a switch mode power supply (SMPS) 15, and an upper pressure control 17. In the timer 24 a square wave pulse train, is generated where the duty ratio can be varied by the delay control 25. This pulse train, in the form of a current, is applied to a capacitor 19 to obtain a ramp voltage. Hence the output of the timer 24 and the input of the SMPS 15 is a voltage increasing with respect to time. The output of the SMPS 15, and therefore the motor voltage and speed, follow the input.

The minimum blower speed is preset so as to give effective operation of the air blower 21 and a minimum airway pressure which is comfortable to the patient. Typically a minimum pressure of 3-5 cm H_2O will have negligible effect on most patients.

The desired maximum airway pressure, being the intended therapeutic airway pressure, is set by adjusting the variable control 17. The magnitude of this pressure will vary according to the requirements of the individual patient but will typically be in the range 10-20 cm H_2O.

When the delay control 25 is not set to zero minutes, the apparatus commences operation at the minimum motor speed and gradually increases the motor speed over a period of time selected before reaching the maximum preselected speed according to the previous adjustment of control 17. When the delay control 25 is set to zero minutes airway pressure comes up to the full level as set by adjustment 17 in a short period of time.

By this arrangement sleep is commenced with a low and comfortable air pressure but then automatically increased after a selectable period of time to the desired therapeutic pressures so as to to provide an adequate pneumatic splint to the airway passages during the latter stages of sleep when apnea is likely.

A convenient way to gauge whether a correct therapeutic, or maximum, pressure has been selected is to use the diagnostic device 10 of this invention while the patient is undergoing CPAP therapy. Should the recorded data show no signs of apneic periods then the setting may be assumed to be adequate at least for the patient when in a similar physical condition. Another long term benefit can be gained by recording the pressure level applied to the patient during sleep periods in which CPAP is applied using the feedback device of this invention. By making such recordings spaced over a period of time the skilled physician can diagnose any long term changes in the patient's condition.

CLAIMS:-

1. A CPAP apparatus including:

a variable pressured air source including an air compressor and means to vary the air pressure delivered therefrom;

a nose piece for sealed air communication with a patient's respiratory system;

an air communication line from the air source to the nose piece;

a sound transducer adapted to be in sound communication with the patient's respiratory system; and

a feedback system controlling the output pressure of the air source in response to an output from the transducer so as to increase the output air pressure from said air source, in response to detection of sound indicative of snoring, in accordance with a predefined procedure.

2. Apparatus in claim 1 wherein the air source is a variable speed air compressor.

3. An apparatus as claimed in claim 2 wherein the feedback control system reduces the output pressure of the compressor in response to an absence of said sound in accordance with a further predefined procedure.

4. An apparatus as claimed in claim 3 wherein the transducer is a microphone rigid with the nose piece so as to receive vibrations caused by patient snoring.

5. An apparatus as claimed in claim 3 wherein the nose piece is a nose mask.

6. An apparatus as claimed in claim 3 wherein the transducer is a microphone enclosed within the nose piece being a nasal prong device.

7. An apparatus as claimed in claim 2 wherein the maximum speed of the air compressor selectable by the feedback control system is adjustably preselected.

8. A variable speed air compressor and control system

for a CPAP apparatus, the control system regulating the speed of the compressor when in use by increasing speed in accordance with a predefined procedure.

9. An air compressor and control system as in claim 8 wherein the predefined procedure includes increasing the speed of the compressor in response to a predetermined signal indicative of patient snoring.

10. An air compressor and control system as claimed in claim 9 wherein the predefined procedure further includes decreasing the speed of the air compressor in the absence of the signal, the decrease in speed being at a preselected rate in accordance with a further predefined procedure.

11. A variable speed compressor and control system as claimed in claim 8 wherein the predefined procedure comprises commencing operation of the compressor at a preselected minimum speed and gradually increasing the speed over a preselected period of time to a preselected maximum speed.

12. A CPAP apparatus including a variable speed air compressor and control system as claimed in claim 10 wherein a compressed air outlet of the air compressor is connected to an air supply line of the CPAP apparatus, the supply line being furthermore connected to a nose piece for air communication to the respiratory system of the patient.

13. Diagnostic apparatus comprising a sound transducer adapted to be positioned in sound receiving communication with the respiratory system of a patient, recordal apparatus connected to the transducer for recording signals produced by the transducer responsive to sounds indicative of snoring patterns of the patient.

14. Apparatus as claimed in claim 13 wherein said signals comprise a processed output from the sound transducer recorded against time and indicating snoring patterns

and/or snoring pattern indexes.

15. In a CPAP apparatus, a sound monitoring device in sound communication with the respiratory system of a patient when using the apparatus, and a control system responsive to output from the sound monitoring device so as to control CPAP pressure according to patient requirements as determined by output from the sound monitoring device.

16. In a CPAP apparatus including a variable speed blower, a nose piece, and interconnecting air lines, a microphone fixed internally of the nose piece so as to be in sound communication with the respiratory system of a patient when using the apparatus, and a control system responsive to output from the microphone so as to control CPAP pressure according to patient requirements as determined by the output from the microphone.

17. A method of diagnosis including applying to a patient before sleep a nose piece containing a microphone connected to a microphone signal recording apparatus, and identifying snoring patterns where indicated by the recorded signal so as to diagnose occurrences of apneic episodes.

18. A method as defined in claim 17 wherein the microphone signals are processed by an electronic processor programmed so as to distinguish predefined snoring patterns and provide signals to the recording apparatus indicative of the occurrence of the predefined snoring pattern.

19. A method of CPAP therapy including

monitoring a patient's snoring patterns using a sound transducer in sound communication with the patient's respiratory system,

identifying predetermined characteristic snoring patterns by electronic analysis of signals from the transducer, and

automatically increasing CPAP pressure delivered to the patient by a predetermined amount responsive to each identified said characteristic snoring pattern.

20. A method as defined in claim 19 wherein CPAP pressure delivered to the patient is automatically gradually decreased in the absence of said characteristic snoring patterns.

21. A method as defined in claim 19 wherein CPAP therapy is commenced at a low CPAP pressure delivered to the patient.

22. A method of CPAP therapy including commencing therapy at a preset minimum CPAP pressure delivered to the patient and then gradually increasing said pressure over a preset period of time to a preset therapeutic pressure.

23. A method of CPAP therapy as defined in claim 19 and further recording pressure levels, against time, delivered to the patient.

24. A method of CPAP therapy as defined in claim 19 and further recording snoring pattern sounds against time so as to confirm correct operation of the CPAP apparatus.

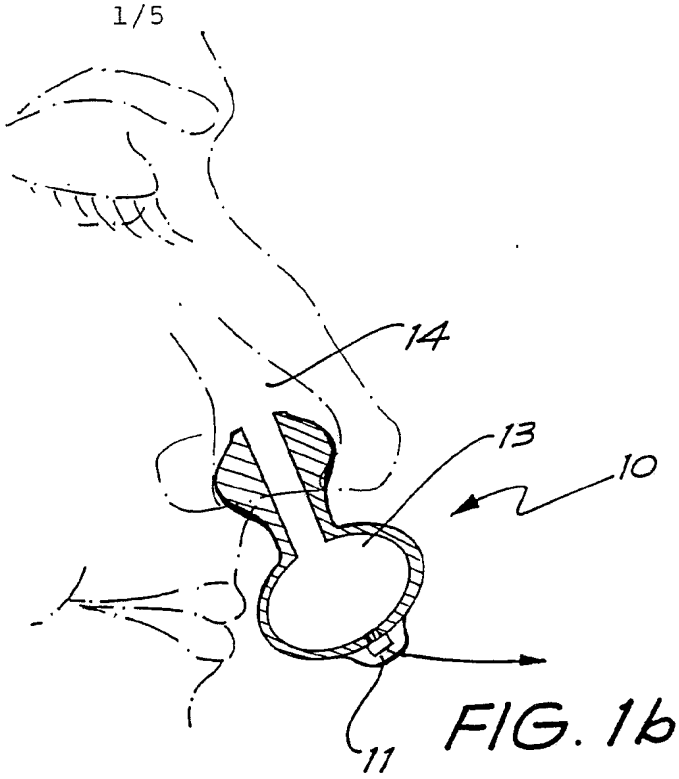


FIG. 1b

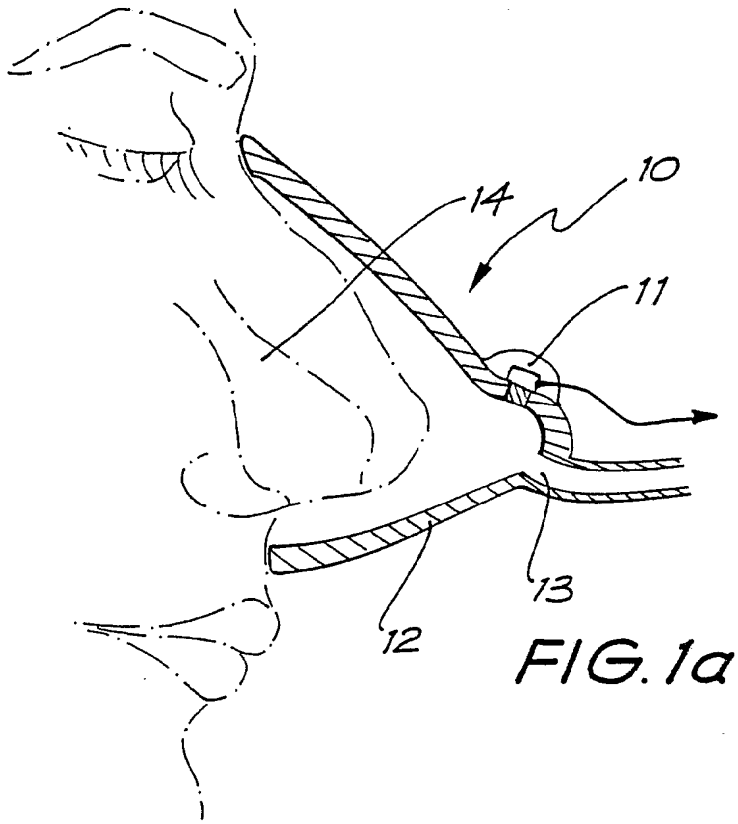


FIG. 1a

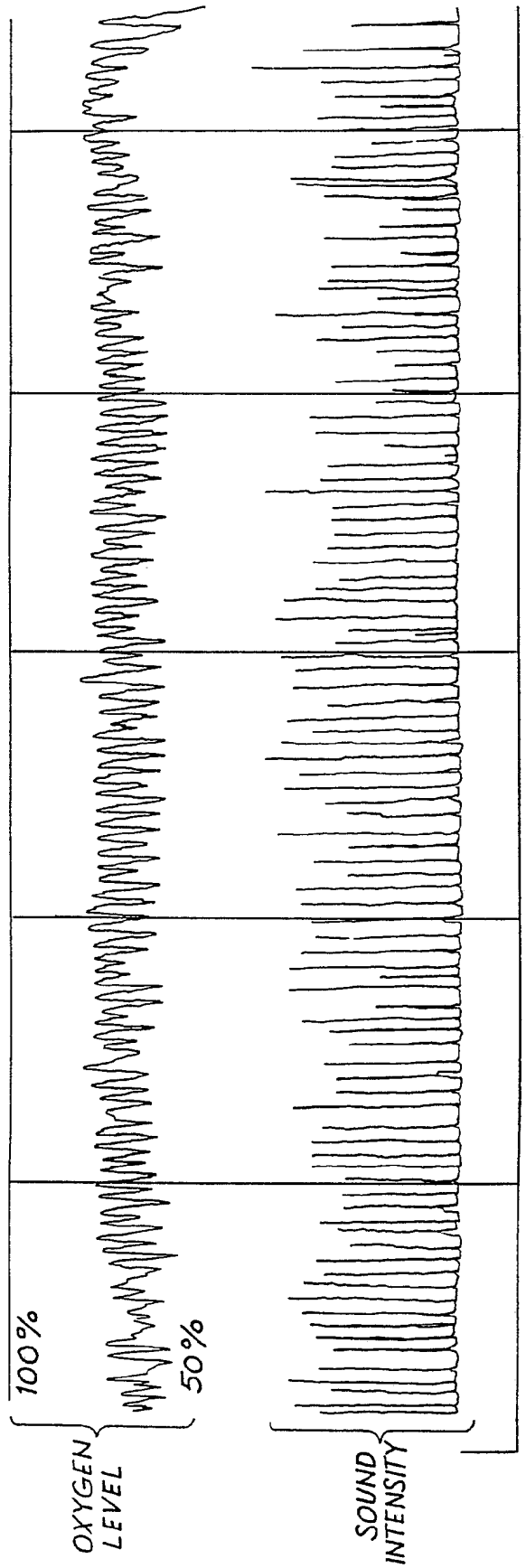


FIG. 2b

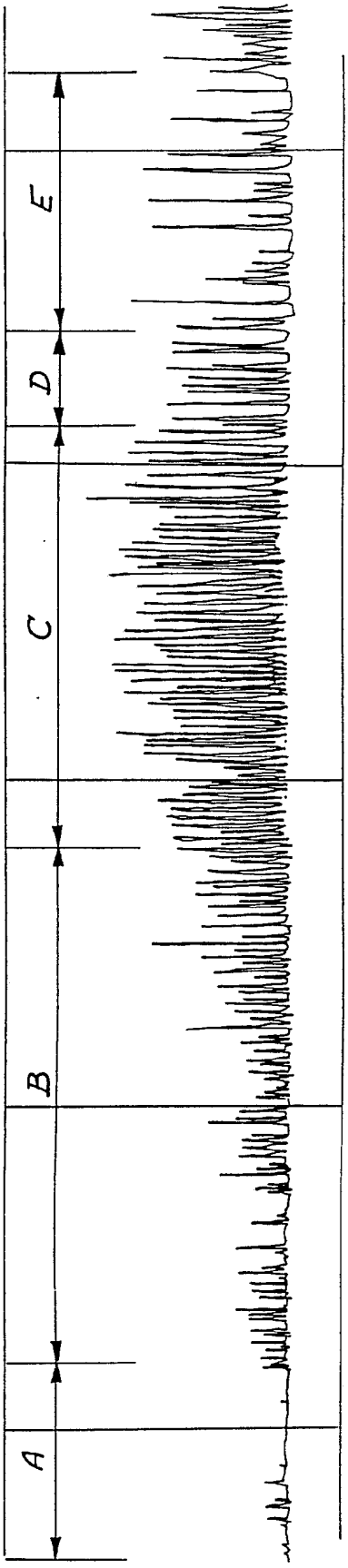


FIG. 2a

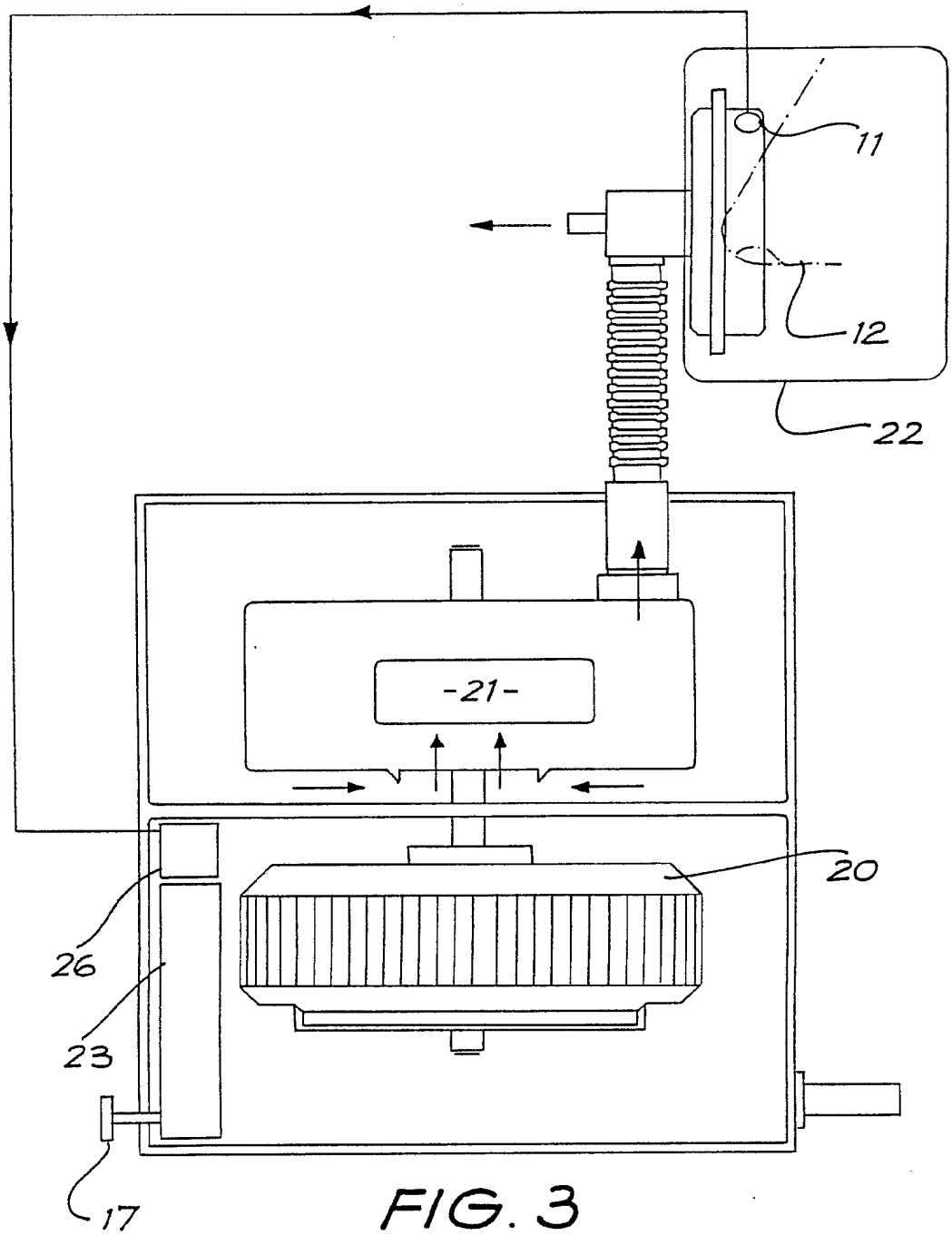


FIG. 3

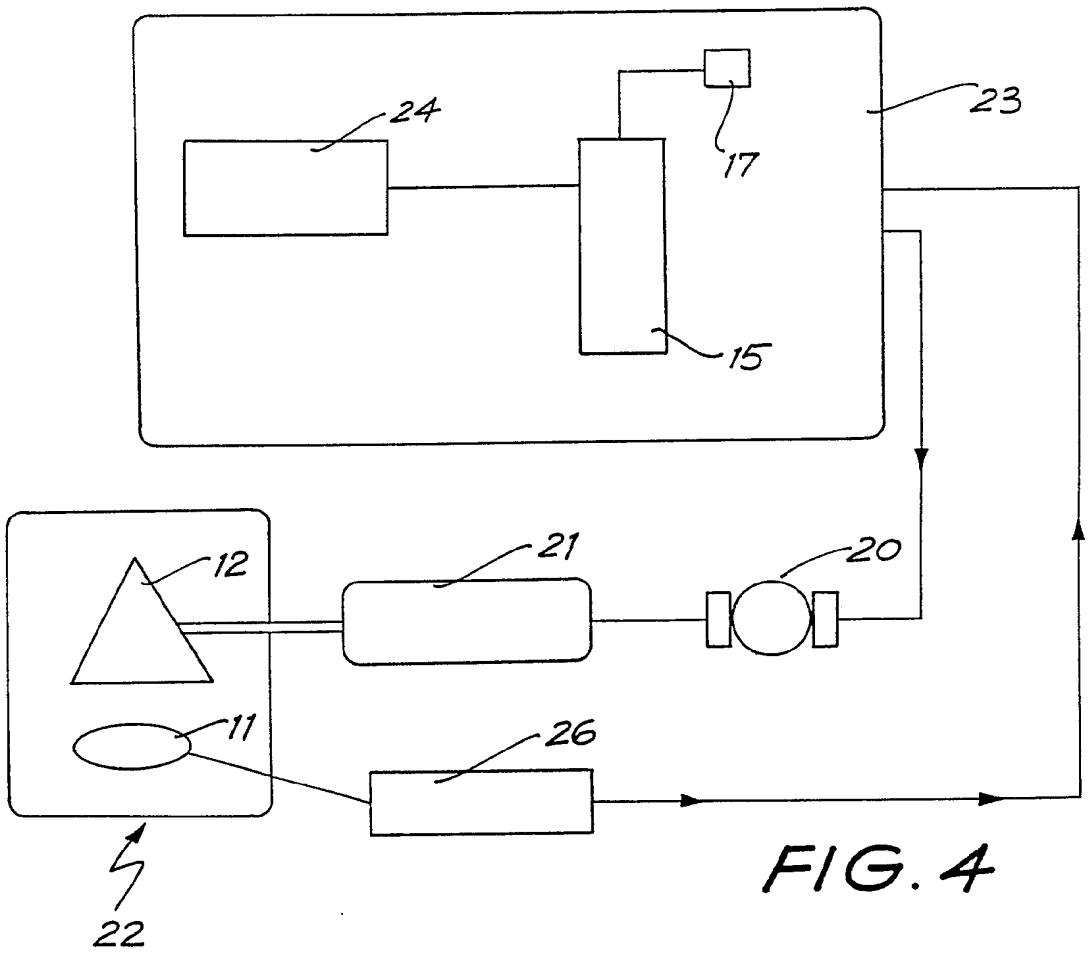
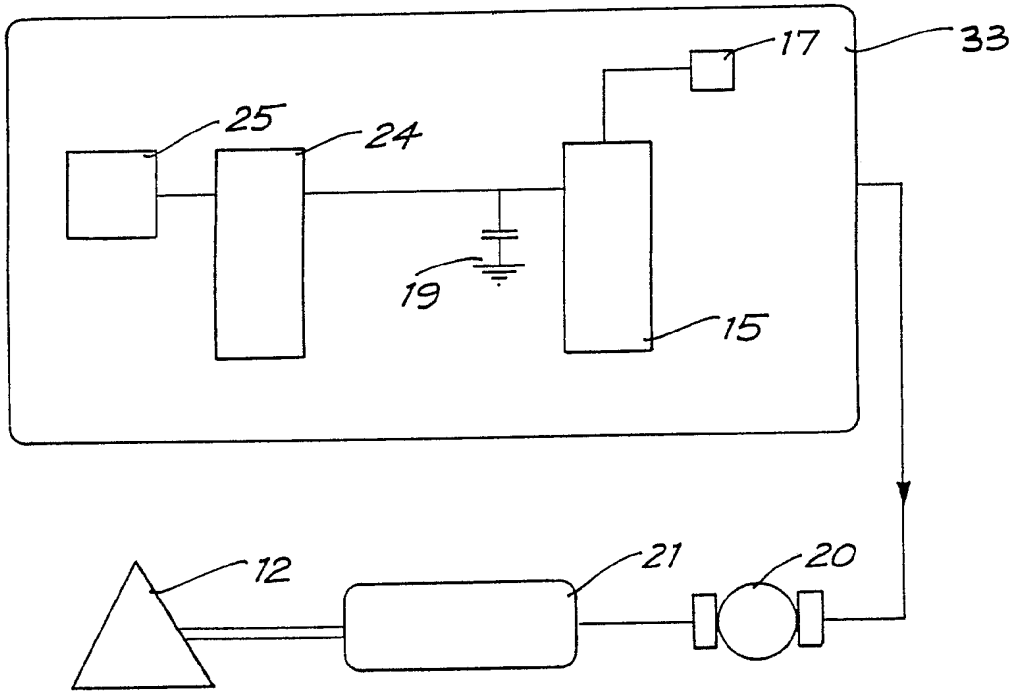


FIG. 4

FIG. 6



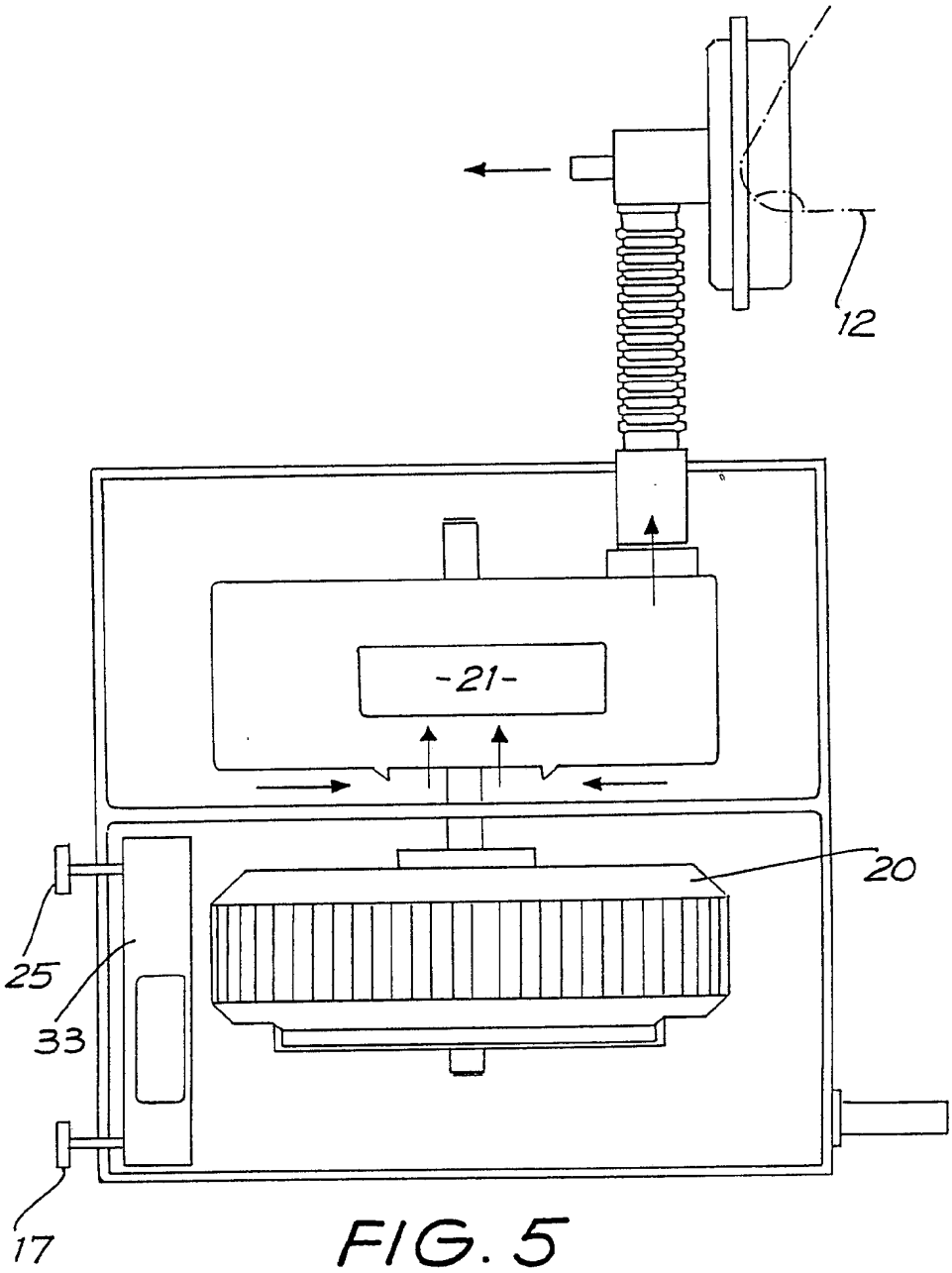


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 88/00215

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61F 5/56, A61B 5/08, F04B 49/06

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
IPC	A61F 5/56, A61B 5/08, F04B 49/06, F04D 27/00
US Cl	128/204.18, 128/204.21, 128/204.23, 128/204.26, 128/205.18

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	WO,A1, 82/03548 (SULLIVAN) 28 October 1982 (28.10.82)	(1-24)
A	US,A, 4630614 (ATLAS) 23 December 1986 (23.12.86)	(1-7,13-24)
A	WO,A1, 87/02577 (PALSGARD et al) 7 May 1987 (07.05.87)	(1-7,13-24)
A	AU,A, 33892/84 (DOWLING) 18 April 1984 (18.04.84)	(1-7,13-24)
X	Derwent Abstract Accession no. 848846/31-16, Class 30a, SU,A, 238077 (GORBUNOVA) 16 July 1969 (16.07.69)	(13,14)
X	EP,A1, 171321 (MEQUIGNON) 12 February 1986 (12.02.86)	(13,14)
X	WO,A1, 86/05965 (EMERGENT TECHNOLOGY CORP.) 23 October 1986 (23.10.86)	(13,14)
A	US,A, 4637386 (BAUM) 20 January 1987 (20.01.87)	(1-12)
X	US,A, 4430995 (HILTON) 14 February 1984 (14.02.84)	(8)
X	US,A, 4347468 (WILKE) 31 August 1982 (31.08.82)	(8)

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search
10 October 1988 (10.10.88)

Date of Mailing of this International Search Report
18 OCTOBER 1988 (18-10-88)

International Searching Authority
Australian Patent Office

Signature of Authorized Officer
A. HENDRICKSON

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically .

3. ☐ Claim numbers. ..... because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

Refer to attached page.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM THE ~~FIRST~~ third SHEET
~~(Not for publication)~~

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING (contd)

Claims 1-7 are directed to a CPAP apparatus comprising a variable pressured air source, a nose piece, an air communication line from the air source to the nose piece, a sound transducer and a feedback system controlling the output of a variable pressured air source in response to the detection of sound.

Claims 8-12 are directed to a variable speed air compressor and control system for a CPAP apparatus.

Claims 13-14 and 17-18 are directed to a diagnostic apparatus and a method of diagnosis comprising a sound transducer and a recording apparatus connected to the sound transducer.

Claims 15-16 and 19-21 are directed to a CPAP apparatus and a method of CPAP therapy comprising a sound monitoring device and a control system responsive to the monitoring device so as to control CPAP pressure.

Claims 22-24 are directed to a method of CPAP therapy including commencing therapy at a preset minimum CPAP pressure and then gradually increasing said pressure over a preset period of time.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 88/00215

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members		
US 4630614	IL 71468	JP 60227730	
AU 33892/84	EP 145160	JP 60100961	US 4644330
EP 171321	FR 2568397		
WO 8605965	EP 218690	US 4686999	
WO 8702577	AU 65236/86	EP 243439	SE 8505040
WO 8203548	AU 83901/82	EP 88761	
US 4637386	BR 8502814 JP 61013971	DE 3422066	EP 164500
US 4430995	AU 84215/82 JP 58029468	EP 66451	GB 2099709

END OF ANNEX